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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,338	11/14/2000	Yoshiyuki Ueno	1110-0279P	3959

7590 01/28/2004

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EXAMINER	
WINKLER, ULRIKE	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/700,338	UENO, YOSHIYUKI	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 November 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Applicants' arguments have been fully considered but they fail to persuade. Applicants' arguments are that the presence of Fas, per se, cannot be used as a general indicator of pathology. Applicants' arguments are that there are contradictory reports in the art regarding the expression of Fas on normal vs. pathological tissue. Applicants cite several references in their response, only those references that have publication dates post the Harada et al. or the Kondo et al. references cited by the Office in the 35 U.S.C. §103 rejection have been evaluated. Applicants cite the Graham et al. as indicating that the there is no change in the Fas/CD95 staining in primary biliary cirrhosis (PBC). For the Office, the important point of the Graham et al. reference is that the PBC cells do express the Fas/CD95, thereby, the reference does not contradict the teaching of the Harada et al. cited by the office in the prior 35 U.S.C. §103 rejection. Harada et al. correlates a strong expression of CD95 in the epithelial cells with the injured bile ducts of PBC (see Harada et al. abstract).

The claims are drawn to a method of preventing **or** treating hepatic cirrhosis **or** bile duct disappearance syndrome using a Fas ligand antagonist. Applicants acknowledge that both the Kondo et al. reference and the Shirakawa et al. reference cited by the Office in the 35 U.S.C. §103 rejection "may suggest or motivate the use of Fas antagonist for treating hepatitis, however, neither reference discloses a relationship between Fas antagonist and hepatic cirrhosis". It is well established in the art that chronic hepatitis leads to hepatic cirrhosis, therefore, a method that will prevent the inflammation and destruction of liver cells (hepatocytes) will prevent the occurrence of hepatic cirrhosis. The claims remain rejected as being unpatentable over Kondo et al. (Nature of Medicine, 1997) in view of Harada et al. (Hepatology 1997, see IDS) and further in view of Shirakawa et al. (U.S. Pat. No. 6,114,507).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294, please note after February 2004 the telephone number will change to 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The official fax phone number for the organization where this application or proceeding is assigned is 703-872-9306; for informal communications please use 703-746-3162, please note after February 2004 the fax phone number will change to 571-273-0912

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JAMES HOUSEL 1/21/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600